

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) ) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
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THIS DOCUMENT RELATES TO: )  
SHEILA BROWN, et al. ) CIVIL ACTION NO. 99-20593  
v. )  
AMERICAN HOME PRODUCTS ) 2:16 MD 1203  
CORPORATION )

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9053

Bartle, J.

May 1, 2013

TaJuan Stout-Mitchell ("Ms. Stout-Mitchell" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2005, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Jesse E. McGee, M.D. Based on an echocardiogram dated April 19, 2002, Dr. McGee attested in Part II of Ms. Stout-Mitchell's Green Form that claimant suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%.<sup>3</sup> Based on

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2. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. McGee also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition is not at issue in this claim.

such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$549,753.<sup>4</sup>

In the report of claimant's echocardiogram, Dr. McGee stated that claimant had "a moderate degree of mitral ... regurgitation." Dr. McGee, however, did not specify a percentage as to claimant's level of mitral regurgitation.<sup>5</sup> Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In June, 2006, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion,

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Claimant also submitted a letter from Keith G. Anderson, M.D., F.A.C.C., who stated that he reviewed claimant's echocardiogram and determined that it demonstrated "moderate mitral regurgitation," which he measured to be 28%.

Dr. Gillespie observed that the "[mitral regurgitant] jet is small and no more than 10% of [the] LAA."

Based on Dr. Gillespie's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Stout-Mitchell's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In contest, claimant submitted a Verified Statement of Dr. McGee wherein he again concluded that claimant had moderate mitral regurgitation with an RJA/LAA of approximately 40%. In support of this conclusion, Dr. McGee stated:

With respect to Mrs. Mitchell's mitral valve regurgitation, I reviewed the Color Flow Doppler portion of the echocardiogram at fifty-five to fifty-nine (55 - 59) seconds, and it objectively demonstrates the level of blue signals originating from the mitral valve and spreading into the left atrium during systole. Based on my education, training, and experience, if the blue signal spreads into the left atrium minimally or at grade 1+, then the patient is suffering from mild mitral regurgitation. If, however, during the echocardiogram, the blue signal spreads into the left atrium at greater than grade 2+, then the patient is suffering from moderate mitral regurgitation. Mrs. Mitchell's echocardiogram clearly and objectively documents a grade grater than 2 +

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Stout-Mitchell's claim.

at fifty-five to fifty-nine (55 - 59) seconds. See Echocardiogram Clip A.

My conclusions were further confirmed as I continued my review of the echocardiogram. At range six minutes and thirty-seven seconds to six minutes and forty-two (6:37 - 6:42) seconds, there is second objective finding that Mrs. Mitchell suffers from moderate mitral valve regurgitation because the echocardiogram objectively documents that Mrs. Mitchell's left atrium mitral valve regurgitation reads at grade 2+. See Echocardiogram Clip B.

These two (2) objective findings clearly demonstrate that Mrs. Mitchell definitively suffers from moderate mitral regurgitation.

The Trust then issued a final post-audit determination, again denying Ms. Stout-Mitchell's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Stout-Mitchell's claim should be paid. On December 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6812 (Dec. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 19, 2007. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor<sup>7</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Stout-Mitchell repeats the arguments she made in contest, namely, that there is a reasonable medical basis for the representation that her echocardiogram demonstrates moderate mitral regurgitation. Specifically, claimant contends there is a reasonable medical basis for her claim because Dr. McGee and Dr. Anderson both reviewed her echocardiogram and concluded that it demonstrated moderate mitral regurgitation. In addition, claimant asserts that the clips identified by Dr. McGee also establish a reasonable medical basis for the representation.

In response, the Trust argues that claimant has failed to establish a reasonable medical basis for her claim because Dr. McGee failed to identify "a holosystolic jet of mitral regurgitation that appears in consecutive frames and meets the 20% ratio required by the Settlement Agreement." In addition, the Trust contends the clips upon which Dr. McGee relies are insufficient because a finding of moderate mitral regurgitation may be made "[o]nly after reviewing multiple loops and still frames."

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Stout-Mitchell had moderate mitral regurgitation. Specifically, Dr. Vigilante observed:

I reviewed the tape and DVD clips of the Claimant's echocardiogram.... This was a below average quality study with the usual

echocardiographic views obtained. The mitral valve was well identified in this study. There were several cardiac cycles in which there could be definite evaluation of the left ventricular endocardium. The Doppler evaluation demonstrated appropriate Nyquist limits of 67 cm per second in the parasternal long axis view and 61 cm per second at a depth of 17 cm in the apical views. However, there was excessive color gain noted during Doppler evaluation particularly in the apical views. In addition, there were only a very few cardiac cycles in which mitral regurgitation was demonstrated in the apical four chamber view. There were no adequate views of mitral regurgitation in the apical two chamber view.

.... There was a thin posteriorly directed jet of mitral regurgitation noted in the parasternal long axis view. The mitral regurgitation jet was best seen in just a few cardiac cycles in the apical four chamber view and not adequately visualized in the apical two chamber view. The mitral regurgitant jet was a thin jet in the apical four chamber view and, visually, only mild mitral regurgitation was present. I digitized the cardiac cycles in which mitral regurgitation could be identified in the apical four chamber view. I digitally traced and calculated the RJA and LAA. I determined that the LAA was 16.9 cm<sup>2</sup>. I determined that the largest representative RJA was 1.8 cm<sup>2</sup>. Therefore, the RJA/LAA ratio was less than 11%, qualifying for mild mitral regurgitation. The RJA/LAA ratio never came close to approaching 20%. I paid particular attention to time frames referenced by Dr. McGee in his Verified Statement. At time frame 0:55-0:59, the parasternal long axis view was present demonstrating a thin posteriorly directed jet of mitral regurgitation. This view was a non-qualifying view for the determination of mitral regurgitation severity. The time frame of 6:37-6:42 was also reviewed. This time frame demonstrated a small jet of mitral regurgitation in the apical four chamber view. In addition, backflow was noted at the beginning of this time frame and was not

representative of mitral regurgitation. In real-time, only mild mitral regurgitation was present. I am unable to determine how Dr. McGee found that an RJA/LAA ratio of approximately 40% was present on this study.

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... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of April 19, 2002 demonstrated mild mitral regurgitation with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.<sup>8</sup>

In response to the Technical Advisor Report, claimant argues that "Dr. McGee is well qualified to review and opine on Mrs. Mitchell's echocardiogram, and that his assessment of her echocardiogram most accurately reflects her cardiovascular condition." She also contends that Dr. McGee, because he is her treating physician, has observed the long-term effects of her ingestion of Diet Drugs. Finally, Ms. Stout-Mitchell asserts that reviewing echocardiograms is not an exact science, demonstrated by the range of RJA/LAA ratios offered in this case.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Contrary to claimant's

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8. Dr. Vigilante also determined that there was no reasonable medical basis for the attesting physician's determination that claimant had a reduced ejection fraction because her echocardiogram demonstrated an ejection fraction of 65%. Under the Settlement Agreement, an ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See Settlement Agreement § IV.B.2.c.(2)(b)iv).

contention, the Verified Statement from Dr. McGee does not establish a reasonable medical basis for his Green Form representation that Ms. Stout-Mitchell has moderate mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, although Dr. McGee submitted a Verified Statement wherein he confirmed his determination that claimant's echocardiogram demonstrated moderate mitral regurgitation, Dr. Gillespie and Dr. Vigilante reviewed claimant's echocardiogram and determined that it demonstrated "no more than 10%" and "less than 11%," respectively.

In addition, Dr. Vigilante reviewed the clips Dr. McGee identified to support his conclusion. With respect to the clip

at 0:55-0:59, Dr. Vigilante observed that the image was of the parasternal long axis view. As noted previously, the Settlement Agreement requires that mitral regurgitation be measured in an apical view. See Settlement Agreement § I.22. Thus, the clip at 0:55-0:59 does not establish a reasonable medical basis for Dr. McGee's representation. With respect to the clip at 6:37-6:42, Dr. Vigilante concluded that it "demonstrated a small jet of mitral regurgitation." Dr. Vigilante also observed that "backflow was noted at the beginning of this time frame and was not representative of mitral regurgitation."<sup>9</sup> Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation. To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

Moreover, to the extent claimant relies on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that she had moderate mitral regurgitation, such reliance is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding

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9. Despite an opportunity to do so, claimant did not respond to these specific determinations by Dr. Vigilante. See Audit Rule 34.

of moderate mitral regurgitation cannot be medically reasonable where the auditing cardiologist estimated that claimant's echocardiogram demonstrated an RJA/LAA ratio of "no more than 10%" and the Technical Advisor, based on his measurements, determined claimant's echocardiogram demonstrated an RJA/LAA ratio of "less than 11%." Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation would allow a claimant to recover benefits with an RJA/LAA ratio that does not meet the requirements set forth Section IV.B.2.c. This result would render meaningless this critical provision of the Settlement Agreement.<sup>10</sup>

Finally, to the extent claimant asserts she is entitled to Matrix Benefits because her condition is a result of her ingestion of Diet Drugs, such assertion is erroneous. Causation is not at issue in resolving claims for Matrix Benefits. Rather, claimants are required to show that they meet the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which

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10. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."

matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. The Settlement Agreement unequivocally requires that claimant suffer from at least moderate mitral regurgitation to receive Level II benefits based on the mitral valve. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion that her ingestion of Diet Drugs is the cause of her heart-related problems is not pertinent to the issue before the court.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Stout-Mitchell's claim for Matrix A-1 benefits.